PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	U.S. Patent 6,733,767
Issued:	May 11, 2004
To:	Rey T. Chern, et al.
Assignee:	Merck Sharp & Dohme Corp.
For:	LIQUID POLYMERIC COMPOSITIONS FOR CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

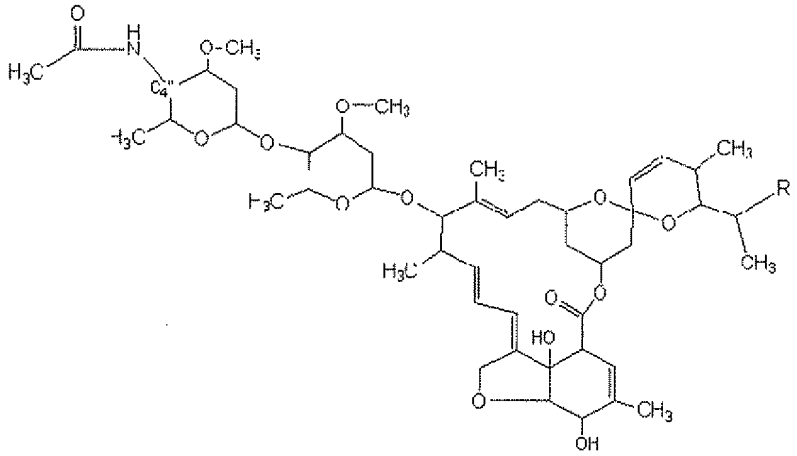
APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Sir:

Your Applicant, Merck Sharp & Dohme Corp., a corporation organized and existing under the laws of the state of New Jersey, represents that it is the assignee of the entire interest in and to Letters Patent of the United States No. 6,733,767 granted to Rey T. Chern, et al. on May 11, 2004 for "Liquid Polymeric Compositions for Controlled Release of Bioactive Substances" by virtue of an assignment in favor of Merck Sharp & Dohme Corp., recorded May 23, 2001, Reel 011833, Frame 0287 (Attachment E).

Your Applicant acting through its duly authorized attorney, hereby submits this application for extension of patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). A copy of the Power of Attorney authorizing Ms. Sylvia A. Ayler to act on behalf of your Applicants is attached hereto as "Attachment A." For the convenience of the U.S. Patent and Trademark Office, the information contained in this application is presented in a format that follows the order of requirements of 37 C.F.R. § 1.740.

(a)(1) The approved product LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide is a macrocyclic lactone and contains as the active ingredient eprinomectin, having the chemical name 4"-deoxy-4"-epiacetylamino-avermectin B_1 and consisting of a mixture of two homologous components, B_{1a} (4"-deoxy-4"-epiacetylamino-avermectin B_{1a}) and B_{1b} (4"-deoxy-4"-epiacetylamino-avermectin B_{1b}). The structural formula for eprinomectin is as shown below:



R

B1a – CH_2CH_3
B1b = CH_3

(2) The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, Section 512 (21 U.S.C. § 360) under INAD Application No. 10708.

(3) The approved product, LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide received permission for commercial marketing or use under Section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360) under New Drug Application (NADA) No. 141-327 on September 26, 2011.

(4) The only active ingredient in LONGRANGE Extended-Release Injectable Parasiticide is eprinomectin which has been previously approved for commercial marketing or use as IVOMEC EPRINEX Pour-On for Beef and Dairy Cattle under Section 512 of the Federal

Food, Drug and Cosmetic Act (21 U.S.C.§ 360), the Public Health Service Act or the Virus-Serum-Toxin Act prior to the approval of NADA No. 141-327.

(5) This Application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f), said period which will expire on November 26, 2011.

(6) The complete identification of the patent for which extension is being sought is as follows:

Inventors: Rey T. Chern and Joel R. Zingerman
Patent Number: 6,733,767
Date of Issue: May 11, 2004
Current Date of Expiration: March 18, 2019.

(7) See "Attachment B" for a complete copy of the patent identified in paragraph (6) hereof.

(8) A disclaimer, attached hereto as "Attachment G" was issued with regard to US Patent No. 6,733,767. No Certificate of Correction or Re-examination Certificate has been issued with regard to US Patent No. 6,733,767. The Maintenance Fee Statement for U.S. Patent No. 6,733,767 is attached hereto as "Attachment C" and indicates that the eighth year maintenance fee was duly paid.

(9) U.S. Patent No. 6,733,767 claims the approved product and a method of using the approved product.

The active ingredient, eprinomectin, is claimed in a composition in Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, and a method of using the composition containing active ingredient, eprinomectin, for the approved use is claimed in Claims 13 and 14.

(9)(i) The following analysis demonstrates the manner in which at least one such patent claim (e.g. Claim 1) reads on the approved product.

Claim 1 reads as follows:

1. A liquid polymeric composition for controlled release of eprinomectin consisting essentially of:

(a) 1 to 10% of eprinomectin;

(b) 1 to 10% of a poly(lactide-co-glycolide) copolymer; wherein the weight ratio of the poly(lactide-co-glycolide) copolymer to the eprinomectin is 1:1 or less and the ratio of lactide:glycolide of the poly(lactide-co-glycolide) copolymer is from about 75:25 to about 65:35; and

(c) at least one lipophilic solvent or a mixture of hydrophilic and lipophilic solvents, wherein the volume ratio of the hydrophilic and lipophilic solvents is from about 80:20 to about 5:95.

The approved product contains eprinomectin which is the active compound in the composition of Claim 1

(9)(ii) The following analysis demonstrates the manner in which at least one such patent claim (e.g. Claim 13) reads on the method of using the approved product, where the claims include any claim to the method of using the approved product.

Claim 13 reads as follows:

A method for the controlled release of eprinomectin in a mammal which comprises injecting said mammal with the composition of any one of claims 1-12.

The approved product LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide is a macrocyclic lactone class anthelmintic/endectoparasiticide, and has been approved for use in cattle on pasture for treatment and control of Gastrointestinal Roundworms [*Cooperia oncophora* (Adults and L_4), *Cooperia punctata* (Adults and L_4), *Cooperia surnabada* (Adults and L_4), *Haemonchus placei* (Adults), *Oesophagostomum radiatum* (Adults), *Ostertagia lyrata* (Adults), *Ostertagia ostertagi* (Adults and L_4, and Inhibited L4), *Trichostrongylus axei* (Adults and L_4), and *Trichostrongylus colubriformis* (Adults)]; Lungworms [*Dictyocaulus viviparous* (Adults)]; Grubs [*Hypoderma bovis*]; and Mites [*Sarcoptes scabiei var. bovis*]; and contains as an active ingredient eprinomectin which is a compound in the composition of Claim 1 as described under the above analysis for Claim 1. The approved product has been proven to effectively protect cattle from reinfection with the following parasites for the indicated amounts of time following treatment: C. oncophora (100d); C. punctata (100d); H. placei (120d); O. radiatum (120d); O. lyrata (120d); O. ostertagi (120d); T. axei (100d); and D. viviparous (150d).

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

(i)(A) Investigational New Animal Drug (INAD 10708) Application for eprinomectin was submitted on February 2, 2000 and the INAD became effective on February 9, 2000.

(B) New Animal Drug Application (NADA 141-327) LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide was submitted on March 30, 2011; and

(C) New Animal Drug Application (NADA 141-327) LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide was approved on September 26, 2011.

(11) As a brief description of the significant activities undertaken by Applicant, Merck & Co., Inc., via its licensee Merial Inc., during the applicable regulatory review period, attached hereto as "Attachment D", is a chronology of the major communications between the Applicant or its licensee, Merial Inc., and the FDA from February 2, 2000 to September 26, 2011.

(12)(A) Applicant is of the opinion that U.S. Patent 6,733,767 is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C. § 156(a)

U.S. Patent 6,733,767 claims a composition of the active ingredient of product LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide, and a method of using the product.

(b) 35 U.S.C. § 156(a)(1)

The term of U.S. Patent 6,733,767 has not expired before submission of this application under 35 U.S.C. § 156(d)(1) for its extension.

(c) 35 U.S.C. § 156(a)(2)

The term of U.S. Patent 6,733,767 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3)

The application for extension is submitted by the owner of record and is in accordance with the requirement of 35 U.S.C. § 156(d) and rules of the U.S. Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4)

The product, LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide, has been subject to a regulatory review under section 512 of the Federal Food, Drug and Cosmetic Act before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A)

The permission for the commercial marketing or use of the product, LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide, after the regulatory review period is the first permitted commercial marketing or use of the product under the provision of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) under which such regulatory review period occurred.

(g) 35 U.S.C. § 156(c)(4)

No other patent has been extended for the same regulatory review period for the product, LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide.

(12)(B) The length of extension of the patent term of U.S. Patent 6,733,767 claimed by Applicant is 1437 days or approximately 3 years, 11 months and 6 days. The length of the extension was determined pursuant to 37 C.F.R. § 1.778 as follows:

(a) According to 37 C.F.R. § 1.778(b), the length of extension is equal to the regulatory review period for the approved product, reduced as appropriate according to paragraphs (d)(1) through (d)(6) C.F.R. § 1.778.

(b) According to C.F.R. § 1.778 (c), the regulatory review period is the sum of:

(A) The number of days in the period beginning on the earlier of the date of a major health or environmental effects test on the drug was initiated or the date on which an exemption under subsection (j) of section 512 of the Federal Food, Drug and Cosmetic Act became effective for the approved animal drug and ending on the date the NADA for the approved product was initially submitted under section 512 of the Federal Food, Drug and Cosmetic Act, and

(B) The number of days in the period beginning on the date the NADA was initially submitted under subsection (j) of section 512 of the Federal Food, Drug and Cosmetic Act and ending on the date the NADA was approved.

The exemption under subsection (j) of section 512 became effective on February 9, 2000. NADA No. 141-327 was submitted to the FDA on March 30, 2011 and approved on September 26, 2011. This application for extension of the term of U.S. Patent 6,733,767 is based on the regulatory review period that ended with the approval of NADA No. 141-327 on September 26, 2011. Therefore, the length of the regulatory review period under 37 C.F.R. § 1.778 (c) is the sum of the period from February 9, 2000 to March 30, 2011 and from March 30, 2011 to September 26, 2011. This is the sum of 4068 days and 180 days, which totals 4248 days.

(c) According to 37 C.F.R. § 1.778 (d)(1)(i), the number of days in the regulatory review period which were on or before the date on which the patent issued must be subtracted from the number of days in the regulatory review period. U.S. Patent No 6,733,767 issued on May 11, 2004. The number of days in the regulatory review period was 4248 days. Subtraction of the period on or before the patent issuance (1554 Days) from the regulatory review period (4248) leaves a reduced regulatory review period of from May 11, 2004 to March 30,

2011 and from March 30, 2011 to September 26, 2011. This is the sum of 2514 days and 180 days, which is 2694 days.

(d) Under 37 C.F.R. § 1.778 (d)(1)(iii), the regulatory review period must be reduced by one-half of the period determined under 37 C.F.R. § 1.778 (c)(1) after that period is reduced in accordance with paragraph (d)(1)(i). As indicated, the period determined under CFR C.F.R. § 1.778 (c)(1) is 4068 days. Subtracting the 1554 days in the period on or before the patent issuance reduces the period in (c)(1) to 2514 days. One-half of 2514 days is 1257 days. Subtracting this amount (1257 days), ignoring half days in the subtraction, from 2694 days (the portion of the regulatory review period that occurred after issuance of the patent) leaves a reduced regulatory review period of 1437 days (37 CFR § 1.778 (d)(1)(iii).

(e) According to (37 CFR § 1.778 (d)(2), the reduced regulatory review period of 1437 days is added to the expiration date of U.S. Patent No. 6,733,767 (March 18, 2019) to give an extended expiration date of February 23,2023 (37 CFR § 1.778 (d)(2)).

(f) According to 37 CFR § 1.778 (d)(3), when 14 years is added to the date of approval of the NADA application under section 512 of the Federal Food, Drug, and Cosmetic Act, (September 26, 2011), this gives a date of September 26, 2025.

(g) According to 37 CFR § 1.778 (d)(4), by comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) and selecting the earlier date, the date for extended expiration of U.S. Patent 6,733,767 is February 23,2023.

(h) The five-year limitation of 35 U.S.C. §156(g)(6)(A) and 37 CFR § 1.778 (d)(5) applies to this application, because U.S. Patent No. 6,733,767 issued after the enactment of the Generic Animal Drug and Patent Term Restoration Act (November 16, 1988). When 5 years is added to the expiration of U.S. Patent No. 6,733,767 (March 18, 2019), this gives a date of March 18, 2024. This date is later than the date obtained according to 37 CFR § 1.778 (d)(4), therefore, under 37 CFR § 1.778 (d)(5), Applicant is entitled to an extension corresponding to the period of from March 18, 2019 to February 23,2023. This is 1437 days, which is the length of extension being claimed. Hence, Applicant is in compliance with 35 U.S.C. §156(g)(6)(A) and 37 CFR § 1.778 (d)(5).

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee as set forth in 37 C.F.R. § 1.20(j)(1) for receiving and acting upon this application for extension is to be charged to Merck Deposit Account No. 13-2755 as authorized in the attached Fee Sheet, which is submitted in duplicate.

(15) Please address all inquiries and correspondence relating to the application for patent term extension to:

Sylvia A. Ayler
Merck Sharp & Dohme Corp.
Patent Department
P.O. Box 2000
Rahway, New Jersey 07065-0907
Telephone: (732) 594-4909
Facsimile: (732) 594-4720

(16) The instant application for extension of patent term with regard to U.S .Patent No. 6,733,767 is being submitted as one original and triplicate copies thereof.

Respectfully submitted,

By _____
Sylvia A. Ayler
Reg. No. 36,436
Attorney for Applicant

MERCK SHARP & DOHME CORP.
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Rahway, New Jersey 07065-0907
(732) 594-4909

Date: November 9, 2011

Attachments:

- "Attachment A" – Power of Attorney
- "Attachment B" - Copy of U.S. Patent Number: 6,733,767
- "Attachment C" - Maintenance Fee Statement for U.S. Patent No. 6,733,767
- "Attachment D"- Chronology of Major Communications with the FDA
- "Attachment E" – Copy of Assignment Abstract for U.S. Patent No. 6,733,767
- "Attachment F" – Copy of FDA Approval for LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide
- "Attachment G" – Copy of Terminal Disclaimer for U.S. Patent No. 6,733,767
- Fee Sheet

CERTIFICATION

The undersigned hereby certifies that this application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and triplicate copies thereof.

By _____
Sylvia A. Ayler
Reg. No. 36,436
Attorney for Applicant

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Date: November 9, 2011